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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,251	12/04/1998	IRVING K. ARENBERG	INTRUS-4	8010

7590

07/29/2003

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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 07/29/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/205,251

Applicant(s)

ARENBERG ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 26-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 26-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/20/03 has been entered.

Election/Restrictions

Newly submitted claims 40-42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant is reminded of the restriction requirement and election in papers number 9-10. The election was directed to figs. 1-3.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-42 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claim Rejections - 35 USC § 112

Claims 1,26-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The range of "greater than 48 hours" is not disclosed in the specification as now claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1, 30, 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No.4,472,394).

Manning et al. disclose the invention substantially as claimed. Manning et al. disclose a drug delivery unit comprised of a biocompatible, biodegradable polymer support and at least one pharmacologically active agent that is placed such that it substantially contacts the round membrane of the middle ear. See page 4, lines 11-14, page 5, lines 9, page 6, lines 24-30. This would encompass the being in direct contact or against and "at least partially in said round window niche". With respect to the

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location of the drug delivery unit, it is disclosed on page 1, lines 19-21 that "access to the inner ear tissue regions is typically through a variety of structures including the round window membrane "... etc. That would narrow it to the location between the tympanic membrane and the round window that is the location of the round window niche since it is also disclosed that the drug delivery unit is in contact with the round membrane of the middle ear. Manning et al. teach that the device provides extended release. See page 4, lines 5-20 and abstract. On page 7, lines 7-12. Manning disclose the drug concentration can be varied over broad limits and is chosen depending upon solubility , pharmacological activity, desirable effect of the end product , patient size and weight all factors know to those skilled in the art. As for the language of the "the biocompatible polymer" it is well known in the art that that would be a synthetic as opposed to a "biopolymer" which is naturally occurring. However, Manning does not disclose the specific time period of greater than a month. Peterson teaches implanting a pellet/ ruminant beneath the ear for extended controlled release of the active ingredient over a period of 60 days to 210 days. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the period of release of the drug of Manning et al. with a period of greater than a month as taught by Peterson in order to provide uniform extended release depending on the parameters (such as weight of patient, type of drug, solubility of drug, etc.) required for a dosing regiment. Further lacking any criticality or unexpected results, it would have been obvious to modify the time period since slow release and controlled release is well

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known in the medical arts when treating the patients with respect to severity of the disease and patient's medical history.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No 4,472,394) and further in view of Husmann et al. (See Hearing Research, Round window administration of gentamicin: a new method for the study of ototoxicity of cochlear hair cells).

Manning et al. in view of Peterson teach all the limitations of the claims except the spaced apart limitation of the drug delivery unit from the round window membrane. See above. Hussman et al. teach and suggest drug delivery units placed and spaced apart from the round window membrane in the analogous art of drug delivery. Hussman et al. disclose a drug delivery unit placed in a desired location within the round window niche. Specifically, it is disclosed that the unit can be placed in the middle ear above or below the columella or in the middle ear directly on the membrane covering the round window, which would encompass the round window niche of the subject. (See 2.2.2.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings and suggestions of Hussman et al. to vary the location of the drug delivery unit spaced apart or in direct contact or completely within the round window membrane because Hussman shows the knowledge generally available to one of ordinary skill in the art with respect to varying the location and placing of the drug delivery unit in the middle ear. The placing of the drug delivery unit in spaced apart and in contact with the middle ear would further bring about a more encompassing research study.

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Claims 29 , 34, 39, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No 4,472,394).

Manning et al. and Peterson disclose the invention as substantially claimed. See above. Manning et al. teach the drug concentration can be varied over broad limits and are chose preferably should be chosen depending upon the solubility, pharmacological activity , desirable effect of the end product, patient size, weight and so forth , all factors known to those skilled in the art. It is further known that quantities are related to the pharmacological characteristic/properties of the drug to be used and further the cost of expensive drugs. However, they are silent to the agent being delivered in microgram or nanogram quantities. It would have been obvious to one of ordinary skill in the art to modify the quantity of the therapeutic agent as inferred by Manning et al. in order to provide a cost effective to the end user and further in consideration to the size of the target site to which the drug would be delivered to.

Response to Arguments

With respect to applicant's arguments, the Examiner is not persuaded since applicant's specification discloses no criticality to the time periods since it is so broadly disclosed.. the now claimed range is more narrow but also not supported as originally filed. Applicant's specification discloses a time period ranging from minutes to hours or many months.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would be obvious in view of the knowledge of one of ordinary skill in the art and that which is well known in research. Further, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

With respect to applicant's argument on page 10 directed at the Peterson reference. The Examiner is not relying on non-degradable silastic silicone rubber implant but rather on the teaching of the controlled released time. The primary reference provides for the biocompatible, biodegradable polymer. The variation of time that applicant claims is still encompassed by the claim language of greater than 48 hours. However, this subject matter is also considered to be new matter.

Conclusion

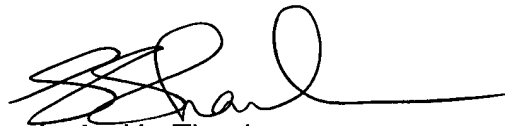
Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is

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(703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', with a long horizontal line extending to the right.

LoAn H. Thanh
Examiner
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LT
July 28, 2003